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EXAMINER	
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ART UNIT	PAPER NUMBER
1203	

DATE MAILED: 10/16/96

#12

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary	Application No. 08/468,792	Applicant(s) D'Amato
	Examiner Garth M. Dahlen	Group Art Unit 1203

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *25-40* is/are pending in the application.

Of the above, claim(s) *27 and 30-32* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *25, 26, and 33-40* is/are rejected.

☒ Claim(s) *28 and 29* is/are objected to.

☒ Claims *25-40* are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- *SEE OFFICE ACTION ON THE FOLLOWING PAGES* ---

Part III: DETAILED ACTION

15) The Examiner acknowledges the election of the species of compound EM-12 in paper #11. Currently claims 25-40 are pending.

Restriction

16A) Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I - drawn to a method of treatment with the instant compounds wherein exactly one of R5, R6, and R8 is -N(Y)-R10 and R9 is formula A) having exactly one of R11-R16 is -N(Y)-R10, classified in Class 514, subclass 323. Claims 26, 28, 29, and 33 are directed thereto.

Group II - drawn to a method of treatment with the instant compounds that are not encompassed by group I above, classified in Class 514, subclasses 183+. Claims 27 and 30-32 are directed thereto.

16B) The methods of using the compounds of the Inventions I and II are independent since the structures of the compounds are so

distinct in structure as to be virtually unrelated. Furthermore, a reference showing the method of using a compound of one invention would not render the same method of using a compound of the second invention prima facia obvious. They are not classified together under the accepted scientific mode of classification and they are capable of supporting separate patents. Restriction for examination purposes as indicated is proper because these compounds are not recognized equivalents in the art.

16C) Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

16D) In accordance with the election of the species of compound EM-12, Group I has been examined. Claims 27 and 30-32 have been

withdrawn from consideration as being drawn to a nonelected invention.

16E) Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

17A) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17B) Claims 25, 26, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goihman-Yahr (Goihman-Yahr, M. Et al, Int. Nac. Dermatol. 1978, 57(4), pages 317-32). The reference teaches the method of using thalidomide (which is encompassed by the instant genus of compounds) to treat mycobacterial infection. The difference between the reference method and the instant is the instant method is for the treatment of undesired angiogenesis and the ~~instant~~ reference is for the treatment of mycobacterial infections. The Examiner concludes that the method of treatment of undesired angiogenesis with the instant compounds is obvious since the treatment of mycobacterial infections is encompassed by the instant method as described in line 8 of page 3 of the instant specification.

17C) Claim 26 is included in the rejection of paragraph 17B above, since the instant compound is an isomer of the reference. It would have been obvious to one having ordinary skill that the instant compounds would be expected to share similar properties with the structurally similar reference compounds. It has been held that a compound which is structurally isomeric with a compound of the prior art is prima facia obvious absent

unexpected results. In re Finley, 81 USPQ 383 (CCPA 1949); In re Norris, 84 USPQ 458 (CCPA) 1950).

17D) Claims 25, 26, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatfill (Hatfill, S.J. et al, Leuk. Res. 1991, 15(2-3), pages 129-36). The arguments of the rejection of paragraph 17B above is incorporated here by reference. Hatfill teaches the treatment of leukemia with thalidomide. The Examiner concludes that the method of treatment of undesired angiogenesis with the instant compounds is obvious since the treatment of leukemia is encompassed by the instant method as described in line 13 of page 5 of the instant specification.

17E) Claims 25, 26, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vogelsang (see PTO-1449, paper #8). The arguments of the rejection of paragraph 17B above is incorporated here by reference. Vogelsang teaches the treatment of graft-vs-host disease with thalidomide. The Examiner concludes that the method of treatment of undesired angiogenesis with the instant compounds is obvious since the treatment of graft-vs-host disease

is encompassed by the instant method as described in line 2 of page 3 (as corneal graft rejection) of the instant specification.

17F) Claim 25, 26, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waters (see PTO-1449, paper #8). The arguments of the rejection of paragraph 17B above is incorporated here by reference. Waters teaches the treatment of ulcerative colitis with thalidomide. The Examiner concludes that the method of treatment of undesired angiogenesis with the instant compounds is obvious since the treatment of ulcerative colitis is encompassed by the instant method as described in line 12 of page 4 of the instant specification.

17G) Claims 25, 26, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mummery (Mummery, C.L. et al, Toxicol. Lett. 1983, 18(3), pages 201-9, the online abstract has been solely relied upon for this rejection). The arguments of the rejection of paragraph 17B above is incorporated here by reference. Mummery teaches the treatment of neuroblastomas with thalidomide. The Examiner concludes that the method of treatment of undesired angiogenesis with the instant compounds is obvious

since the treatment of neuroblastomas is encompassed by the instant method as described in line 4 of page 5 of the instant specification.

17G) Claim 25, 26, 33, 34, 36, 37, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over De (De, A. U. et al, J. Pharm. 1975, 64(2), pages 262-6) in view of each of the references of Folkman (see PTO-1449, paper #8) and Gimbrone (see PTO-1449, paper #8). The arguments of the rejection of paragraph 17B above is incorporated here by reference. De teaches the treatment of neoplasts with thalidomide and thalidomide derivatives. The Examiner concludes that the method of treatment of undesired angiogenesis with the instant compounds is obvious since Folkman teaches that tumors grow via angiogenesis and Gimbrone teaches that neovascularization occurs in association with angiogenesis.

17H) Claim 25, 26, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graudums US 3,705,162 in view of Folkman (see PTO-1449, paper #8). The arguments of the rejection of paragraph 17B above is incorporated here by reference. Graudums

teaches the antitumor effect with thalidomide derivatives. The Examiner concludes that the method of treatment of undesired angiogenesis with the instant compounds is obvious since Folkman teaches that tumors grow via angiogenesis.

17I) Claim 25, 26, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gutierrez-Rodriguez (Guiterrez-Rodriguez, O. et al, J. Rheumatol. 1989, 16(2), pages 158-63, the online abstract has been solely relied upon) in view of Colville-Nash (see PTO-1449, paper #8). The arguments of the rejection of paragraph 17B above is incorporated here by reference. Gutierrez-Rodriguez teaches the treatment of rheumatoid arthritis with thalidomide. The Examiner concludes that the method of treatment of undesired angiogenesis with the instant compounds is obvious since Colville-Nash teaches that rheumatoid arthritis is an angiogenesis-dependent disease.

18A) Claims 25, 26, 34, and 36-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of 08/168,817, now allowed. Although the conflicting claims are not identical, they are not

patentably distinct from each other because the claim of '817 is drawn to a method of treating angiogenesis with thalidomide which is a compound encompassed by the instant genus and is an isomer of the compound of instant claim 26.

18B) Claim 35 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of 08/371,987, now allowed. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '987 are drawn to a method of treating angiogenesis with a composition comprising the compounds of instant claim 25 and an epoxide hydrolase inhibitor.

19) Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no teaching or guidance in the specification or the art of record as to the scope of the compounds encompassed by the phrase, "thalidomide metabolite or hydrolysis product."

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~~18~~) The references that were cited in the PTO-1449, paper #8, but were not submitted have not been taken into consideration, specifically AF-AI, AK-AP, AT, BP-BS, CA, CF-CH, CJ-CN, CQ, CT, CV, and DA. The submission of these documents is requested in order to facilitate prosecution.

21
~~19~~) Claims 28 and 29 are objected to for being dependent upon a rejected base claim; however, the claims would be allowable if rewritten in independent form.

ALLOWABLE SUBJECT MATTER:

22
~~20~~) Claims 28 and 29 would be allowable if rewritten in independent form. The art containing the compounds most closely related to the instant is found in De. The method of treating undesired angiogenesis using the 3-aminothalidomide as in claim 28 and the 3-hydroxythalidomide as in claim 29 is allowable since there is no teaching or suggestion within the art of record to modify the thalidomide derivatives of De to have the instant radicals at the 3-position.

23
~~18~~) The drawings have been objected to by the Draftsperson under 37 CFR 1.84 or 1.152, see the attached form PTO 948. Correction is required.

24
~~19~~) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Garth Dahlen, Ph.D. whose telephone number is (703) 308-4608.

C. Warren Ivy
Supervisory Patent E
Group 120

GD
Garth M. Dahlen

October 4, 1996